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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
02/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,290	HOLTET ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. This application is a 371 of PCT/GB04/01572. For applications filed under 371, PCT rules for lack of unity apply.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-17. Claims 1-3, 22-23, 30, drawn to a trimeric polypeptide comprising three monomers which are members of the TNF ligand superfamily, each member is selected from the group consisting of: LTA; TNF; LTB; TNFSF4; TNFSF5; TNFSF6; TNFSF7; TNFSF8; TNFSF9; TNFSF10; TNFSF11; TNFSF12; TNFSF13; TNFSF13B; TNFSF14; TNFSF15; and TNFSF18.

Groups 18-60. Claims 1, 4-9, 22-23, 30, drawn to a trimeric polypeptide comprising three monomers which are members of the TNF receptor superfamily, each member is selected from the group consisting of: TNFRSF1 A, TNFRSF 1 B, LTBR, TNFRSF4, TNFRSF5, TNFRSF6, TNFRSF6B, TNFRSF7,TNFRSF8, TNFRSF9, TNFRSF 10A, TNFRSF 10B, TNFRSF 10C, TNFRSF 10D, TNFRSF11A, TNFRSF11B, TNFRSF12, TNFRSF12L, TNFRSF13B, TNFRSF13C, TNFRSF 14, TNFRSF Fnl4, NGFR, TNFRSF 17, TNFRSF 18,

TNFRSF 19, TNFRSF 19L, TNFRSF21, TNFRSF22, TNFRSF23, a polypeptide encoded by a DNA sequence selected from the group consisting of TNFRSF 1B D1 D2 (SEQ ID NO: 13), TNFRSF1B D1D2, 1/6 (SEQ ID NO:15), TNFRSF1B D1D2 1/4 (SEQ ID NO:17), TNFRSF1B D1D2, 1/3 (SEQ ID NO:19), TNFRSF1B D1D2, 1/2 (SEQ ID NO:21),TNFRSF1B D1D4 (SEQ ID NO:23), TNFRSF1B D2 (SEQ ID NO:25), TNFRSF1B D2, 1/6 (SEQ ID NO:26), TNFRSF1B D2, 1/4 (SEQ ID NO:27), TNFRSF1B D2, 1/3 (SEQ ID NO:28), TNFRSF1B D2, 1/2 (SEQ ID NO:29), and TNFRSF1B D2D4 (SEQ ID NO:30).

Groups 61-69. Claims 1, 10-14, 22-23, 30, drawn to a trimeric polypeptide comprising three monomers which are antibodies, each monomer is selected from the group consisting of: MAb 1 (ECACC 89080301), MAb 21 (ECACC 90012432), MAb 25 (ECACC 89121401), MAb 32 (ECACC 89080302), MAb 37 (ECACC 89080303), MAb 42 (ECACC 89080304), MAb 47 (ECACC 89121402), MAb 53 (ECACC 90012433) and MAb 54 (ECACC 89083103).

Groups 70-72. Claims 1, 15-16, 22-23, 30, drawn to a trimeric polypeptide comprising three monomers which are proteins having the scaffold structure of C-type lectin-like domains (CTLD) wherein the monomer having the scaffold structure of C-type lectin-like domains is selected from the group consisting of TN3-2-B (SEQ ID NO:103), TN3-2-C (SEQ ID NO:104) and TN3-2-D (SEQ ID NO: 105).

Groups 73-76. Claims 1, 17-23, 35, 30, drawn to a trimeric polypeptide comprising three monomers comprising a trimerising domain derived from tetranectin, the monomer selected from the group consisting of TN-2-B (SEQ ID NO:106), TN-2-C (SEQ ID NO:108), TN-2-D (SEQ ID NO:107), and AD1D4-GSS-I10 (SEQ ID NO:109).

Groups 77-152. Claims 24-25, 29, 32-34, drawn to a method of treatment by administering a trimeric polypeptide comprising three monomers, the monomer selected from the group consisting of: LTA; TNF; LTB; TNFSF4; TNFSF5; TNFSF6; TNFSF7; TNFSF8; TNFSF9; TNFSF10; TNFSF11; TNFSF12; TNFSF13; TNFSF13B; TNFSF14; TNFSF15; TNFSF18; TNFRSF1 A, TNFRSF 1 B, LTBR, TNFRSF4, TNFRSF5, TNFRSF6, TNFRSF6B, TNFRSF7,TNFRSF8, TNFRSF9, TNFRSF 10A, TNFRSF 10B, TNFRSF 10C, TNFRSF 10D, TNFRSF11A, TNFRSF11B, TNFRSF12, TNFRSF12L, TNFRSF13B, TNFRSF13C, TNFRSF 14, TNFRSF Fnl4, NGFR, TNFRSF 17, TNFRSF 18, TNFRSF 19, TNFRSF 19L, TNFRSF21, TNFRSF22, TNFRSF23, a monomer encoded by a DNA sequence selected from the group consisting of TNFRSF 1B D1 D2 (SEQ ID NO: 13), TNFRSF1B D1D2, 1/6 (SEQ ID NO:15), TNFRSF1B D1D2 1/4 (SEQ ID NO:17), TNFRSF1B D1D2, 1/3 (SEQ ID NO:19), TNFRSF1B D1D2, 1/2 (SEQ ID NO:21),TNFRSF1B D1D4 (SEQ ID NO:23), TNFRSF1B D2 (SEQ ID NO:25), TNFRSF1B D2, 1/6 (SEQ ID NO:26), TNFRSF1B D2, 1/4 (SEQ ID NO:27), TNFRSF1B D2, 1/3 (SEQ ID NO:28), TNFRSF1B D2, 1/2 (SEQ ID NO:29), TNFRSF1B D2D4 (SEQ ID NO:30); MAb 1 (ECACC 89080301), MAb 21 (ECACC 90012432), MAb 25 (ECACC 89121401), MAb 32 (ECACC 89080302), MAb 37 (ECACC 89080303), MAb 42 (ECACC 89080304), MAb 47 (ECACC 89121402), MAb 53 (ECACC 90012433); MAb 54 (ECACC 89083103); TN3-2-B (SEQ ID NO:103), TN3-2-C (SEQ ID NO:104); TN3-2-D (SEQ ID NO: 105); TN-2-B (SEQ ID NO:106), TN-2-C (SEQ ID NO:108), TN-2-D (SEQ ID NO:107), and AD1D4-GSS-I10 (SEQ ID NO:109).

Groups 153-168. Claims 26-28, drawn to a method of preparation of a trimeric polypeptide comprising three monomers, said method comprising the steps of (i) culturing a host

transformed with a vector encoding said trimeric polypeptide under such conditions that said trimeric polypeptide is expressed; and (ii) isolating said trimeric polypeptide and wherein said monomer comprises an amino acid sequence selected from the group consisting of TNFRSF 1B 1-235 (SEQ ID NO:76), TNFRSF1B 1-185 (SEQ ID NO:77), TNFRSF1B 1-163 (SEQ ID NO:78); TNFRSF1B 1-142 (SEQ ID NO:79); a polypeptide comprising an amino acid sequence encoded by a DNA sequence selected from the group consisting ofTNFRSF1B D1D2 (SEQ ID NO:13), TNFRSF1B D1D2, 1/6 (SEQ ID NO:15), TNFRSF1B D1D2 1/4 (SEQ ID NO:17), TNFRSF1B D1D2, 1/3 (SEQ ID NO:19), TNFRSF1B D1D2, 1/2 (SEQ ID NO:21), TNFRSF1B D1D4 (SEQ ID NO:23), TNFRSF1B D2 (SEQ ID NO:25), TNFRSF1B D2, 1/6 (SEQID NO:26), TNFRSF1B D2, 1/4 (SEQ ID NO:27), TNFRSF1B D2, 1/3 (SEQ ID NO:28), TNFRSF1B D2, 1/2 (SEQ ID NO:29) and TNFRSF1B D2D4 (SEQ ID NO:30).

Group 169-245. Claim 31, drawn to an assay method for detecting a trimeric cytokine in a sample.

NOTE: Should any one of the Groups from 1-245 be elected, Applicants are required to select one polypeptide of specific amino acid sequence (SEQ ID NO). Once one polypeptide of specific amino is selected, all other sequences will be withdrawn from consideration.

NOTE:Claims 3, 5, 9, 12, 16, 21 encompass polypeptides that are not related in structure and function. Claim 1 is not a proper linking claim because it, in fact, comprises multitudes of polypeptide sequences.

NOTE: Applicants must choose a single polypeptide sequence for examination. This is not a species election, but an election of a single invention.

NOTE: Claim 29 embraces "use" of the trimeric polypeptide and there are no provisions for "a use" in the statutes. Applicants are requested to amend the claim to delete this limitation.

The inventions listed as Groups I-245 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since WO 01/64889 (XENCOR) teaches non-naturally occurring monomeric TNF-alpha variant proteins which can be used as TNF-alpha antagonists. The monomeric TNF-alpha variant proteins disclosed in the reference are characterized by having at least one amino acid substitution as compared to the wild-type TNF-alpha sequence. The monomeric TNF-alpha variant proteins when administered to a patient, interact with the wild-type TNF-alpha to form mixed trimers which are incapable of activating receptor signaling (see Fig. 1A and 1B and claims 12-13). The trimeric protein of the reference meets the limitations of the trimeric polypeptide of Group I. Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention.

The inventions of Groups 1-17 are patentably distinct from the products of Groups 18-76, because the products of Groups 1-17 are structurally and functionally different from the products of Groups 18-76. Similarly, the inventions of Groups 1-76 are patentably distinct from the method of Groups 153-168 because the products of Groups 1-76 can be synthesized by a materially different method, such as by chemical synthesis. The inventions of Groups I-76 are patentably distinct from the methods of Groups 77-152, 169-245 because the products of Groups 1-76 can be used in methods that are materially different from the methods Groups 77-152, 169-245, such as in a method of immunoaffinity chromatography. The methods of Groups 77-245 are patentably distinct from each other because each recites method steps not required by the other, each method uses different starting materials and the search of all methods in one patent application would result in an undue search burden.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Election of species

4. This application contains claims directed to the following patentably distinct species of disease mediated by TNF of the claimed invention:

If any one of Groups 72-152 is elected Applicants are required to elect one of the following species of disease mediated by TNF selected from:

rheumatoid arthritis, psoriasis and Crohn's disease.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 24, 29, 32-34, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646